Data Access Agreement for Work to be Performed by Organizations of the MINZDRAV (Russian Ministry of Health; Federal Department for Medical, Biological and Extreme Problems) and MINATOM (Russian Ministry of Atomic Energy) under the Agreement Between the Government of the Russian Federation and the Government of the United States of America on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment (JCCRER Agreement)

Project 2.1

METABOLISM AND DOSIMETRY OF PLUTONIUM INDUSTRIAL COMPOUNDS

INTRODUCTION

The purpose of this data access agreement is to ensure that Russian and American scientists working on projects under the Agreement Between the Government of the Russian Federation and the Government of the United States of America on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment (JCCRER Agreement) have equal access to all primary and original Russian and American data necessary to conduct the work described under Directions 1 and 2 of the JCCRER Agreement. Such access will ensure the highest quality of scientific research conducted in an atmosphere of mutual trust and cooperation.

GENERAL PROVISIONS

1. For the purposes of this agreement on data access, data is defined as all information, in whatever format or media, that is identified by the Principal Investigators and Directors of Participating Institutes as necessary to carry out the project.

2. Privacy statutes in Russia and the United States generally restrict access to data which includes personal identifiers. Individual data, however, is the basis of much of the research work of the JCCRER. Therefore, where necessary, adherence to these statutes will be ensured by substituting unique numerical identifiers which protect individual privacy while allowing analysis of individual and aggregate data.

3. Data covered by this access agreement include original or raw data, compiled data created before these projects were begun, and second generation or summarized data and information compiled according to project requirements. The specific project agreement provisions will specify the actual data which fall under each of these categories. Appropriate access to all these data must be ensured; however, original or raw data, and compiled data created before these projects were begun remain the property of that organization and that country where the data were obtained and are currently maintained.

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4. Secondary data created as part of JCCRER projects, which are a joint scientific product, will be jointly owned by the Russian and the American institutions participating in the project. Each project will determine what is a scientific product of the collaboration and therefore subject to joint ownership.

5. Project participants have the right to appropriate access to original, compiled and secondary data on the territory of the organization which owns and maintains the data.

6. The specific project agreement provisions will identify the kind and extent of unpublished primary, compiled and secondary data that may be transferred out of the country of ownership to achieve specific project goals such as technical analyses, modeling, etc. at the home institution of researchers. When such data transfers occur, they must also be approved in writing by the Director of the institute or organization to which the data belong. Transferred data cannot be used for purposes other than those specified by the agreement, even after the project is completed or the researcher is no longer associated with the JCCRER. In cases where such data are transferred to people who are not participants in the project for the purposes of furthering the project, the same conditions and limitations on use of data apply. Such transfers will be carefully scrutinized.

7. No transfers, publications, presentations, press releases or any other form of communication to the outside world regarding details of the unpublished data or the unpublished results of studies conducted under the authority of the JCCRER will be made without the written consent, and participation of the institutions maintaining the data sets and the scientists involved in the research. Any agreement to make data publicly available must be approved by the Directors of organization performing the research. Scientists and specialists participating as current members of the JCCRER Joint Committee, Executive Committee and Scientific Review Groups have a right to review data and unpublished results of studies as appropriate to their responsibilities but are similarly bound by the restrictions on communication as described in this paragraph.

8. Dissemination of scientific results, in the form of presentations at scientific meetings and publications in referred journals, is regarded as an essential product of the JCCRER work. To ensure that such communications take place while complying with the requirements of the participating institutions and funding agencies, procedures will be developed for the expeditious review and approval of such communication requests from the principal investigators.

9. Data published in the open, peer-reviewed literature shall be referenced and used according to generally understood and accepted conventions of scientific conduct; it is expected that proper reference and credit to the origin of the published material will be made.

10. After the publication of reports, third parties may request access to unpublished study data that does not contain individual identifiers, in order to conduct independent analyses. Third parties are defined as experts in the fields of radiation health effects and dosimetry who are not part of any JCCRER project. Procedures will be developed for requesting and approving such third party access to primary data.

PROJECT 2.1 DATA ACCESS AGREEMENT: SPECIFIC PROVISIONS

INTRODUCTION

The main purpose of Project 2.1 is detailed study of the biokinetcis of actinide elements (especially Pu-239) in humans through joint and collaborative analysis and interpretation of data accumulated by the Dosimetry Registry of the Mayak Industrial Association (DRMIA) and U.S Transuranium and Uranium Regristries (USTUR). The data include personal and occupational histories, actinide exposure and dosimetry information, medical history and autopsy reports, and the results of postmortem analysis of tissues from deceased workers from nuclear facilities in the United States and the Russian Federation.

PERSONS WITH RIGHTS OF ACCESS TO PROJECT 2.1 DATA

In addition to those specified in item 7 of the General Provision, above, as having access to the data, access to original, and previously compiled data is granted to the Russian and American scientists participating in Project 2.1.

The primary and previously compiled data are the property of the organization generating them. Each registry will maintain ownership and control over the original data collected by them for the purposes of quality control of derived data. No transfer of the primary documents will be made. For the purposes of Project 2.1 collaborative research, American and Russian Project participants have a right of appropriate access to primary and previously compiled data at the site of the organization which owns and maintains them.

DATA COVERED BY THIS ACCESS AGREEMENT

This agreement covers the data described below. It does not apply to reports, papers, oral presentations, or other open literature presentations generated independently by the USTUR or FIB-1 and involving only their respective data. Neither shall this agreement apply to data, information, documents or analyses produced by either Registry for purposes outside of the scope of Project 2.1.

Original Data

This category includes documents containing data on the personal, medical, and work histories of cases from both Registries, such as dates of birth, employment, and death; and dates of actinide contamination or exposure incidents. Also included are medical data obtained during life, autopsy reports, and anthropometric data (e.g., body height and weight and organ weights) as well as the original results of radiochemical analysis of body organs

and tissues. Personnel dosimetry data including external dosimetry, the results of in-vivo evaluations of actinide uptake, and the results of analysis of excreta and other bioassay samples are included in this category.

Compiled Data Created Before the Beginning of Project 2.1

This category includes the databases created by each Registry before the beginning of Project 2.1 which contain original data as stated above and the results of various analyses of these data including such derivative data as actinide content of tissues, organs, excreta and estimates of total body intake, uptake and excretion as well as the cause of death, medical histories and dosimetry

Data Compiled for this Project

This category includes the database created as a part of this project for the purpose of performing the tasks concerning metabolism of plutonium and americium in the human body, and values derived from calculations involving the original or compiled data described above. Derived data might be in the form of ratios, sums, differences, and averages of original or compiled data or the products and quotients of original or compiled data and mathematical constants. Data derived from this database will be freely shared among the American and Russian Project 2.1 investigators with no formal permissions required.

DATA THAT MIGHT BE REMOVED FROM THE COUNTRY OF ORIGIN

This secondary database described above is considered to be jointly owned by FIB-1 and the USTUR and all or parts of it may be shared and transferred from one site to the other with the written permission of the managers of the two organizations.

Unpublished, summarized data may be sent or taken to the U.S. or Russian Federation for the purpose of finishing and submitting joint progress reports to financial sponsors or for submitting joint publications to peer-reviewed scientific journals.

APPROVALS

Valentin Khokryokov		Principal Investigator, Russia
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Frank Hawkins	11/30/98	Office Director, Office of International Health Programs, U.S. Department of Energy